

Attorney Docket No.: 1-1997,341 US D1
U.S.P.T.O. Customer No.: 31846

IV. Remarks and Conclusion

Applicant extends his thanks to the Examiner for correcting the restriction requirement. Claims 30, 31, 34, and 36 are presently pending. Claim 30 has been amended to limit the Claim to vaccines comprising *E. risticii* strains that have the 85 kilodalton gene, the gene that causes the strain to be immunogenic, not heretofore known. Claim 36 has been added. Support for Claim 36 can be found on page 55 of the application, in the Summary and results section.

A. Specification Objections

In response to the objections to the specification, Applicant has made the requested typographical corrections. No estoppel should result from these amendments.

B. Drawing Objections

In response to the objection to the drawings, Applicants enclose replacement sheets for all of the drawings. No new matter has been added.

C. Sequence Listing Objections

In response to the Notice to submit a sequence listing, Applicant has fully complied. A separate page is enclosed for the sequence listing.

D. Rejections under 35 USC §112, 2nd ¶

In response to the rejection under 35 USC §112, 2nd ¶, as Claims 28-35 being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, Applicant respectfully requests reconsideration based on this response.

Attorney Docket No.: I-1997341 US D1
U.S.P.T.O. Customer No.: 31846

To begin the Examiner asserts the claims are unclear for recitation of "essentially the same antigenic characteristics of *E. risticii* 90-12. The Examiner questions which characteristics. Applicant respectfully requests removal of the rejection in light of this response.

In brief, the characteristic that Applicant discovered is a variance in the 90-12 strain, as is documented in the Background of Invention Section, that causes then strain to be immunogenic. The Examiner has recognized that the 90-12 strain and the 25-D strain are antigenically different, but Applicant has discovered an immunogenic difference that allows the 90-12 strain to be more efficacious than the vaccine strains known in the art as of the filing of this patent application. Accordingly, Applicant is claiming the immunogenic characteristic of the 85 kilodalton (kD) gene of an *E. risticii* strain. Applicant has amended Claim 30 to recite "[a] vaccine comprising an immunogenically effective amount of a killed *E. risticii* strain having an 85 kilodalton gene and a pharmaceutically acceptable carrier or diluent." Accordingly, Applicant has specifically claimed the antigenic characteristic that imparts immunogenic characteristics. Therefore, Applicant respectfully requests removal of the rejection. Section 112, 2nd paragraph, only requires that the claim be sufficiently definite and that the applicant set forth what is claimed. Here, both have been met and the rejection should be removed.

E. Rejections under 35 USC §112, 1st ¶

Claims 28-35 stand rejected under 35 USC §112, 1st ¶, for written description. This claim has been obviated, as Applicant has amended. Applicant has amended Claim 30 to recite "[a] vaccine comprising an immunogenically effective amount of a killed *E. risticii* strain having an 85 kilodalton gene and a pharmaceutically acceptable carrier or diluent." Support for this amendment can be found in SEQ ID NO's 3 and 4; Examples 1, 2, and 3; and, throughout the Detailed

Attorney Docket No.: 1-1997341 US D1
U.S.P.T.O. Customer No.: 318216

Description. Accordingly, there is written description supporting the amendment and Applicant respectfully requests that the rejection be removed.

Claims 28-35 further stand rejected under 35 USC §112, 1st ¶ as non-enabled. In light of the amendments above, Applicant respectfully requests reconsideration. Applicant has shown efficacy of strain of *E. risticii* with a 85 kD gene. Accordingly, Applicant respectfully requests reconsideration.

G. Rejections under 35 USC §102

Claims 28-31 stand rejected under 35 USC §102(b) as anticipated by a 1995 article to Vemulapalli. The Examiner contends that the article discloses the 25D and the 90-12 strain of *E. risticii*. Further, the Examiner contends that these strains would have the same antigenic characteristics as the 90-12 strain. As well, the Examiner contends that the article disclosed the administration of an effective amount of a vaccine comprising strain 90-12 to mice and then challenging, which resulted in protection. In light of the amendments and further argument, Applicant respectfully requests reconsideration. The limitations of Claim 32 were incorporated into Claim 30.

Claims 28-31 stand rejected under 35 USC §102(b) as being anticipated by a 1992 article to Shankarappa. The Examiner contends that the article discloses that *E. risticii* and *E. sennetsu* are antigenically closely related, that they have essentially the same antigenic characteristics. In light of the amendments and following argument, Applicant respectfully requests reconsideration.

To begin, the basic premise of the Examiner's rejection is incorrect. It cannot be said that strains that are antigenically related are in any manner immunogenically related. Antigenicity and

Attorney Docket No.: 1-1997,341 US 01
U.S.P.T.O. Customer No.: 31846

immunogenicity are two separate characteristics, not closely related. Here, the *E. sennetsu* has not been shown to be an *E. risticii* strain that possess the 85 kD gene. Accordingly, this article does not anticipate the amended Claims. Reconsideration is respectfully requested.

Lastly, Claims 28-35 stand rejected under 35 USC §102(h) By US Patent No. 4,759,927. The Examiner contends that the patent discloses chemically inactivated *E. risticii* that imparts protection against Potomac Horse Fever. In light of the following response, Applicant respectfully requests reconsideration.

First, Applicant is very aware of this patent, as the first named inventor is the same as the first named inventor on the present application. In fact, the present application makes reference to this prior art vaccine and the differences with the 90-12 strain. Applicant has now determined the immunogenic characteristic that differentiates the claims of the present vaccine as compared to the claims of the prior art patents. None of the cited references teach or suggest a vaccine antigen as claimed by Applicant. In fact, this application and its parent, US Pat. No. 6,375,954, are different, as the '927 patent does not have an 85 kD gene as claimed by Applicant. Accordingly, Applicant respectfully requests reconsideration.

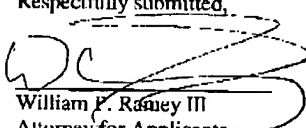
V. Conclusion

In conclusion, Applicants respectfully assert that the application is in a condition for allowance and request such action. Should any fees be required in this or any subsequent action, the Patent Office is hereby authorized to charge deposit account 02-2334. Applicant respectfully requests an interview with the Examiner to facilitate allowance of the Claims. Further Applicant respectfully petitions for a one-month extension of time, the fee for which may be charged to deposit account 02-

2334.

Attorney Docket No., 1-1997,341 US D1
U.S.P.T.O. Customer No.: 31846

Respectfully submitted,



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